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Medwatch of the FDA

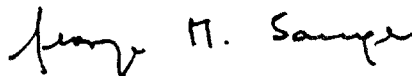
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July 7, 2000

Dear Sir,

I read in the media that the FDA is considering to let drugs that lower cholesterol (statins) be obtained over the counter. This caused me to have alot of concern. I myself have had problems with Mevacor, Zocor and Lipitor. They have consisited of muscle aches and stiffness in the lower extremities which I have attributed to a form of myopathy. Thes symptoms have partially disappeared on dicontinuing the drugs. Two of my friends have reported more severe muscular side-effects leading to disabling pain and loss of power in both upper and lower extremities. My CPK values have been normal. I think that the fact that CPK is normal has led a lot of physicians to deny the presence of myopathy and do not report the true incidence of myopathy, attributing the symptpms to the "stiffness of old age". I know that this report of side effects is anecdotal but, I understand that a controlled double-blind study of side effects with muscle biopsies and measurements of muscle strength is under way. I would strongly urge you to await the publication of the outcome of this study before releasing any of the statin drugs for sale in the OTC market.

Yours truly,



George M. Sanger M.D.

Retired Member of AMA and ACOG

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